



Integrated Clinical Systems, Inc.

Janus Phase 2 Deployment User Acceptance Test Report in the Staging Environment

Description

System Title:	WebSDM/Janus User Acceptance Testing for Janus Phase 2 Deployment in the Staging Environment			
Client Organization:	NCI			
Client Project Manager:	Christo Andonyadis	Christo Andonyadis		
IBM Project Manager:	Mary Ferramosca			
Lincoln Project Manager:	Sally Cassells			
ICS Project Manager	Eric Herbel			
FDA Project Manager:	Bobbie Witczak			
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Version History

Rev Number	Date	Ву	Description of Changes
1.0	12/04/2007	Mary Ferramosca	Initial Draft
2.0	12/06/2007	Bob Stephens	Editorial changes
3.0	12/11/2007	Mary Ferramosca	Corrections made to Testing Summary Table and Deviations Table

Review/Acceptance Table:

Person Reviewing/ Approving	Date	Comments
Sally Cassells (Lincoln Technologies)	12/11/2007	
Mary Ferramosca – Project Manager (IBM)	12/11/2007	
Eric Herbel (Integrated Clinical Systems)	12/11/2007	
Bobbie Witczak - (FDA)		
Christo Andonyadis (NCI)		

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1. Introduction

The objective of this User Acceptance Test Report is to document the testing results achieved by the FDA staff during the testing of the Integrated JANUS system prior to the launch of the FDA operational pilot. This testing was done in the Staging environment. This work is part of the work for the Janus Phase 2 Deployment project funded by the NCI.

The scope of functionality tested under this plan and documented in this report includes major end user functions of the JANUS system. Specifically, the end user functions tested include

- Loading submissions data using the sftp link between the FDA and NCI systems.
- o Administering User accounts.
- Accessing JReview using the JANUS Materialized Views and the WebSDM Integration Server single sign-on service.
- Using WebSDM with JANUS Materialized Views and the WebSDM Integration Server single sign-on service.

Details of the data loading test activities closely follow the tasks described in the document titled "Use Case Model Survey for EDR-Janus Interface (SFTP Solutions), Updated 8/24/2007 (v6)."

These testing activities are needed in order to prepare for the FDA's Operational JANUS Pilot.

2. Testing Summary

Test Case	Functionality Tested	Version	Tester	Date	Passed/Failed	Vendor
1	Data loading with valid data.	1.0	Gini Khalsa and Bobbie Witczak	November 29, 2007	Р	LTI
2	Data loading with load errors.	1.0	Gini Khalsa and Bobbie Witczak	November 29, 2007	Р	LTI
3	User Account Administration.	1.2	Bobbie Witczak	November 30, 2007	Р	LTI

Test Case	Functionality Tested	Version	Tester	Date	Passed/Failed	Vendor
4	JReview with JANUS Materialized Views.	9.0.3.2	Bobbie Witczak	November 30, 2007	Initially 52 Pass, 10 Fail. After configuration changes were made, all passed.	ICS
5	WebSDM with JANUS Materialized Views.	1.0	Bobbie Witczak	November 29, 2007	34 Pass 1 Fail	LTI

3. Deviations

The significant deviations from the original test plan were:

Test Script	Description of Deviation	Resolution
Script 3	Apache server unavailability	LTI created user name and password.
Script 4	Sections 51-60 were not completed due to data not appearing	Configuration changes made and retesting performed. All passed after configuration changes were made.
Script 5	Access to WebSDM application failed due to Apache server unavailability	User logged in manually.

3.1 Assumptions, Exclusions, and Limitations

The assumptions that affect the level of assurance gained from the system testing are:

- JANUS loading test cases include both cases where the data is expected to successfully complete the full 'end-to-end' of the loading process and cases that demonstrate different aspects of the error handling functionality.
- For purposes of user testing of the actual JANUS loading, a small study was used in order for the loading to occur quickly.
- The WebSDM and JReview application installations in the User Acceptance
 Test environment have undergone their standard Installation Qualification and
 Operational Qualification tests in the Staging environment. The goal of the
 User Acceptance testing of these applications is the assurance that FDA
 reviewers and staff will be able to use these applications to view studies using
 the JANUS materialized views as the data source.

The limitations during the system testing were:

- Scripted JANUS loading tests did not use data from actual FDA submissions due to the high severity of data errors encountered during the validation process that precluded loading actual data.
- The staging environment was not ready for use until 2 days before the UAT was scheduled to be completed. Therefore, not all the testers could be scheduled to participate.

4. Conclusions

The UAT testing occurred during the last week of November 2007. The UAT testing occurred in the staging environment. The testers were given scripts to follow in order to look at the study through the applications. The applications predominantly worked as designed. There were a few deviations noted that are listed above in section 3.

5. External References

Document	Accessible At
EDR Interface Use case V6	
Janus Production Deployment Diagram	JANUS G-Forge Website
Study Data Tabulation Model Dataset Validation Requirements	JANUS G-Forge (http)